RESPONSE

Claims 13-17, and 30 remain in the present application. Claims 13, 17, and 30 are in independent form.

Applicants express their gratitude for courtesies extended by the Examiner during a personal interview with Applicants' representative, Dr. Kenneth I. Kohn, conducted August 21, 2003. During the interview, amendments to the pending claims were discussed.

According to the Office Action, claims 13 and 17 are still rejected under 35 U.S.C. § 102(b) as being anticipated by Sato, et al. as evidenced by Petre, et al. In response to the rejection, Applicants have amended independent claims 13 and 17 pursuant to suggestions set forth in the Office Action. The claims have been amended to include the limitations set forth in dependent claim 29, which was examined and not rejected in view of the cited prior art. The claims specifically claim a composition that is stable for at least one year at 2°C to 8°C and that elicits immunity to weaned pigs for at least six months. Since Sato, et al. does not teach an antigen composition that it stabilized for at least one year at 2°C to 8°C and does not provide immunity to weaned pigs for at least six months, the presently pending independent claims are patentable over the cited prior art reference. Reconsideration of the rejection is respectfully requested.

Presently pending claims 16, 28, and 30 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In response thereto, claim 28 has been cancelled and claim 30 has been amended to specifically

identify and describe the goods associated with the trademarks "TWEEN 80™" and "SPAN 80™." Additionally, claim 16 has been amended by replacing "X" with the word "fold." Reconsideration of the rejection is respectfully requested.

Claims 17 and 29 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. In response thereto, Applicants have amended claim 17 pursuant to suggestions set forth in the Office Action and have cancelled claim 29. Claim 17 has been amended to include the specific limitations set forth in the Office Action regarding the enablement of the claimed vaccine composition. In other words, the vaccine composition includes a 10 fold concentrated fluid fraction from an *E. rhusiopathiae* culture that is inactivated with formalin or beta propiolactone, 30% v/v aluminum hydroxide gel as a stabilizing agent, and an adjuvant composition including 10% lecithin in mineral oil, 5.6% polysorbate and 2.4% sorbitan monooleate in phosphate buffered saline. Moreover, the vaccine composition provides immunity to weaned pigs after storage at 2°C to 8°C for at least six months. As a result of the amendment to claim 17 and cancellation of claim 29, reconsideration of the rejection under 35 U.S.C. § 112, first paragraph is respectfully requested.

Claims 13-15 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Zarkasie, et al. According to the Office Action, Zarkasie, et al. teaches a vaccine composition comprising protected antigens for *E. rhusiopathiae* from whole broth culture and aluminum hydroxide gel, which vaccine conferred various degrees of protection in mice. However, presently amended independent claim 13 is not anticipated by Zarkasie, et al. Zarkasie, et al. does not disclose an antigen composition that is stable at 2°C to 8°C for at least one year and provides

immunity to weaned pigs for at least six months. Additionally, Zarkasie, et al. teaches the addition of an aluminum gel long after obtaining the fluid fraction of the *E. rhusiopathiae* culture. It is well known in the art that adjuvants are added to vaccine compositions a long period of time after obtaining the fluid fractions. Thus, absent evidence to the contrary, Zarkasie, et al. teaches the addition of the aluminum gel to the fluid fraction of the *E. rhusiopathiae* after a long period of time. In contradistinction, the present invention provides for the addition of the stabilizing agent (e.g., aluminum phosphate gel, calcium phosphate gel, etc.) immediately after the supernatant fraction is taken from the fluid fraction of the *E. rhusiopathiae* culture. This provides for immediate hindrance of the degradation of the antigenic potential of the *E. rhusiopathiae* culture. Due to the above differences and that the limitations set forth in claim 13 are from examined and non-rejected claim 29, the presently pending claims are not anticipated by Zarkasie, et al. and are patentably distinct over the prior art. Reconsideration of the rejection is respectfully requested.

Claims 13, 14, and 24 are also rejected under 35 U.S.C. § 102(b) as being anticipated by Groschup, et al. According to the Office Action, Groschup, et al. teaches an antigenic or vaccine composition comprising a culture supernatant antigen of *E. rhusiopathiae* that is obtained from inactivated *E. rhusiopathiae*. According to the Office Action, the antigenic or vaccine composition protects mice against *E. rhusiopathiae* infection challenge. Further, the composition reacted with sera from pigs convalescent from *E. rhusiopathiae* infection.

The present invention, as set forth in the presently amended claims, is not anticipated by Groschup, et al. Groschup, et al. does not teach an antigen composition that includes an *E. rhusiopathiae* culture fluid fraction and a stabilizing

agent (e.g., metal hydroxide, metal phosphate, aluminum hydroxide gel, etc.), wherein the composition is stable at 2°C to 8°C for at least one year and provides immunity to weaned pigs for at least six months. Again, the limitations in the pending claims incorporate limitations set forth in examined and non-rejected claim 29. Thus, the presently pending claims are not anticipated by Groschup, et al. and are patentable over the cited prior art. Hence, reconsideration of the rejection is respectfully requested.

Claims 13, 16, 17, and 25-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Zarkasie, et al. As previously discussed, the present invention is clearly patentably distinct from the vaccine composition disclosed by Zarkasie, et al. Zarkasie, et al. does not disclose nor suggest that the vaccine composition is stable at 2°C to 8°C for at least one year and provides immunity to weaned pigs for at least six months. Due to these claimed differences, the presently pending claims are not obvious in view of Zarkasie, et al. Reconsideration of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

Claims 13, 16-18, and 28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Dayalu, et al. in view of Sato, et al., Zarkasie, et al., and Barenholz, et al. According to the Office Action, one of ordinary skill in the art at the time the invention was made could replace the *E. rhusiopathiae* antigen in the vaccine composition disclosed in Dayalu, et al. with the *E. rhusiopathiae* culture filtrate antigen disclosed in Sato, et al. to produce the vaccine composition of the present invention with a reasonable expectation of success. Furthermore, the Office Action holds that one skilled in the art would have been motivated to produce the instant invention for the expected benefit of advantageously providing a vaccine

composition that comprises protected antigens of *E. rhusiopathiae* because culture filtrate antigens are known in the art to serve as protected antigens as taught by Zarkasie, et al.

As previously argued, the claimed invention is patentably distinct from the antigen/vaccine composition disclosed by Sato, et al. and Zarkasie, et al. Since the cited prior art references do not disclose an antigen/vaccine composition that includes an *E. rhusiopathiae* culture fluid fraction and a stabilizing agent (e.g., a metal hydroxide, a metal phosphate, an aluminum hydroxide gel, etc.), wherein the composition is stable at 2°C to 8°C for at least one year and provides immunity to weaned pigs for at least six months, the presently pending amended claims are patentably distinct over the cited prior art references. The limitations added to the claims are from previously examined and non-rejected claim 29. Reconsideration of the rejection is respectfully requested.

Claims 17, 28, and 30, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Dayalu, et al. in view of Groschup, et al., or Zarkasie, et al., and Barenholz, et al. According to the Office Action, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the *E. rhusiopathiae* antigen extract in the vaccine composition disclosed in Dayalu, et al. with the culture filtrate antigen of *E. rhusiopathiae* culture disclosed in Groschup, et al., or Zarkasie, et al. to produce the vaccine composition of the present invention. Additionally, the Office Action holds that substituting one antigenic composition in a vaccine with another alternative, art-known antigen composition that advantageously comprises protective antigens of *E. rhusiopathiae* would have been obvious to one skilled in the art and would have brought about similar, if not better results.

In response thereto, the presently pending claims have been amended with regard to the antigen composition (i.e., ten fold concentrated *E. rhusiopathiae* fluid fraction, etc.), adjuvant composition (i.e., 10% lecithin in mineral oil, etc.), stabilizing agent (i.e., an aluminum hydroxide gel), and composition stability and protective immunity (i.e., wherein the vaccine composition is stable at 2°C to 8°C for at least one year and provides immunity to weaned pigs for at least six months). Since the cited prior art references do not disclose or suggest the presently claimed invention, the presently pending claims are not obvious in view of the cited prior art references. Hence, reconsideration of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

The remaining dependent claims not discussed above are ultimately dependent upon at least one of the independent claims discussed above. No prior art reference makes up for the deficiencies of that reference as applied against the independent claims as no prior reference discloses or suggests the invention as set forth in the independent claims, as discussed in detail above. Such a combination of references that derive the present invention can only be made through hind sight as no prior art reference discloses or even suggest the fusion protein of the present invention, as discussed in detail above.

In view of the above, the application is in condition for allowance which allowance is respectfully requested.

If any remaining issues exist, Applicants respectfully request to be contacted by telephone at 248-539-5050.

U.S. Patent Application Serial No. 09/489,711
Attorney Docket No. 3153.00050/PC10299A

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Kenneth I. Kohn, Reg. No. 30,955
30500 Northwestern Hwy., Ste 410
Farmington Hills, Michigan 48334
(248) 539-5050

Dated: August 29, 2003

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being transmitted via facsimile (703) 308-7939 to the Patent and Trademark Office on August 29, 2003.

Marie M. DeWitt